

PRODUCT REGULATORY COMPLIANCE STATEMENT

HI5748

Issuance Date: 30 August 2024

HIGH DENSITY POLYETHYLENE

Product Manufacturer

This product is manufactured by Lotte Chemical Titan (M) Sdn Bhd.

REACH (Regulation (EC) No. 1907/2006) and amendments (June 2024)

Substances of Very High Concern (SVHC)

This product does not contain any of the Annex XIV candidate substances (241 substances, 27 June 2024) proposed to be Substances of Very High Concern above the 0.1% threshold as stated in REACH (Article 57, Regulation (EC) No. 1907/2006).

This product also does not contain any substances on the REACH Annex XVII Restriction Substances list (73 valid entries, 1 August 2024).

REACH registration

Polymers are generally exempted from the provisions on registration of Title II of REACH (Article 2(9)). However the ethylene and propylene monomers have to be registered. For further enquiries, please contact our Technical Service Department.

Food Contact

US Food and Drug Administration (FDA)

This product, as manufactured, is in compliance with Title 21 (Edition 2021), Code of Federal Regulations (CFR) Parts 177.1520 (a) (3) (i) (a) (1) and (c) 3.1a & 3.2a as promulgated by the US Food and Drug Administration (FDA) for all food types listed in Table 1 and under conditions of use B through G as described in table 2 of CFR 21 176.170 (C).

European Union (EU) Food Contact – Regulation 1935/2004/EC and (EU) No. 10/2011 and amendments, most recent amendment No. 2023/1627 (August 2023)

This product complies with the relevant requirements of Regulation 1935/2004/EC (Framework Regulation), applicable to plastic raw material.

This product complies with the relevant requirements of Regulation 2023/2006/EC (Good Manufacturing Practice), applicable to plastic raw material. Lotte Chemical Titan maintains an ISO 9001 system that corresponds to the requirements of EC No 2023/2006 and adopts good manufacturing practice.

The monomers and additives used to produce this product are listed in the Union List of Authorized Substances of Regulation 10/2011/EC.

This product contains one or more substances with Specific Migration Limits (SMLs). As the fabrication process can affect the migration behavior, the fabricator of the articles is responsible to test and determine the migration limit of the final articles intended to come into contact with foodstuffs.

This product contains Calcium Stearate (E470a) as dual use additive, which is permitted as food additives or flavourings in Regulation 1333/2008/EC or Regulation 1334/2008/EC.

To obtain information on restricted substances identity, please contact our Technical Service Department.

China National Standard of Food Safety – GB4806.1-2016, GB4806.7-2023 and GB9685-2016

This product complies with the relevant requirements of GB4806.1-2016: General Safety Requirements for Food-Contact Materials and Articles and GB4806.7-2023* Plastic Materials and Products for Food Contact, listed in Table A1 with unrestricted requirements.

*In-house lab test

The monomers and additives used to produce this product are listed in GB9685-2016: Standard for The Use of Additives for Food Contact Materials and Articles and control well below the maximum allowable limit.

This product contains one or more substances with Specific Migration Limits (SMLs). As the fabrication process can affect the migration behavior, the fabricator of the articles is responsible to test and determine the migration limit of the final articles intended to come into contact with foodstuffs.

Japan Food Sanitation Law (Law number: Act No. 233 of 1947)

This product is listed in the Positive List of Polymer of Japan Food Sanitation Act (November 2023). The monomers and additives used to produce this product are listed and control below Use Level listed in Positive List of Monomers and Additives of Japan Food Sanitation Act.

Malaysia Food Regulation 1985

The manufacture of this product complies with the relevant requirements of Malaysia Food Regulation 1985 Part VI Packages For Food, applicable to packages raw material.

As the fabrication process can affect the migration behavior, the fabricator of the articles is responsible to test and determine the migration limit of the final articles intended to come into contact with foodstuffs.

Indonesia Food Contact (BPOM)

This product is in compliance with the Badan Pengawas Obat dan Makanan (BPOM) Regulation 20/2019 on Food Packaging (Appendix I: Food contact substances prohibited for use in food packaging and Appendix II: Food contact substances permitted for use in food packaging with migration limit).

This product does not contain any food contact substances in food packaging with Specific Migration Limits (SMLs).

Heavy Metals

No heavy metals (i.e. antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium) are intentionally added to this product in quantities that would violate government guidelines. The summation of Lead, Mercury, Cadmium and hexavalent chromium in this product is less than 20ppm. Polybrominated biphenyls (PBB), Polybrominated diphenyl ether (PBDE), Hexabromocyclododecane and Phthalates are not intentionally added to this product. This product therefore meets the relevant requirements of the following Directives or Regulations:

- Restriction of Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) – EU Directive 2011/65/EC and amendments (August 2024)
- Coalition of Northeastern Governors (CONEG) Model Toxics in Packaging
- Packaging and Packaging Waste 94/62/EC and amendment (May 2018)
- Waste Electrical and Electronic Equipment (WEEE) – EU Directive 2002/96/EC and 2012/19/EU
- End of Life Vehicles (ELV) – EU Directive 2000/53/EC

Regulation (EC) NO.1895/2005

The manufacture of this product does not involve addition of Bisphenol A (BPA), diglycidyl-ether (BADGE), Bisphenol F diglycidyl ether (BFDGE) and Novolac glycidyl ethers (NOGE).

California Proposition 65 (1986)

The manufacture of this product does not involve addition of any of the substances listed in California's Proposition 65 chemicals listing (29 December 2023).

Halogenated Flame Retardants

This product is not intentionally manufactured with halogenated or phosphorous based flame retardants.

Ozone Depleting Chemicals (ODCs)

This product is not intentionally manufactured with Class I and Class II ODCs listed in the US Clean Air Act Amendments of 1990.

Animal Derived Material/BSE/TSE

This product is not intentionally manufactured with animal fats, oils, milk products or other animal- or tallow-derived products.

Carcinogenic/Mutagenic/Reprotoxic Substances

This product is not intentionally manufactured with carcinogenic 1A/1B, mutagenic 1A/1B or reprotoxic 1A/1B (CMR) substances, in accordance with the classification rules of Regulation (EC) No 1272/2008 (CLP) Annex VI.

Global Automotive Declaration Substance List (February 2023)

This product does not contain any prohibited substances or declarable substances above the threshold limit of 0.1%.

Toys

EN 71-3:2019+A1:2021, EU Directive 2009/48/EC

The manufacture of this product does not involve addition of allergenic fragrances, aluminium, antimony, arsenic, barium, boron, cadmium, chromium (III), chromium (VI), cobalt, copper, lead, manganese, mercury, nickel, selenium, strontium, tin, organic tin and zinc. However, aluminium is a functional component of the co-catalyst system, triethyl aluminium.

EN71-9:2005

The manufacture of this product does not involve addition of chemicals listed in Tables 2D, 2E and 2I

Standard Consumer Safety Specification for Toy Safety ASTM F963

The manufacture of this product does not involve addition of Di(2-ethylhexyl) phthalate, nitrosamines, lead, antimony, arsenic, barium, cadmium, chromium, mercury, selenium.

Food Allergens

The manufacture of this product does not involve addition of food allergens as listed in:

- US Allergen Labelling and Consumer Protection Act of 2004. 21 note – FALCPA and
- EU Regulation No 1169/2011 (25 October 2011) Annex II.

Conflict Minerals

The manufacture of this product does not involve addition of tin, tantalum, tungsten, gold and minerals associated with these metals (Columbite-Tantalite, Cassiterite, Gold, Wolframite)

Nanomaterial

This product is not a nanomaterial.

Persistent Organic Pollutants

This product is not intentionally manufactured with chemical substances as listed in Regulation (EU) 2019/1021 and amendments.

Global Chemical Inventory Compliance

All ingredients of this product are listed in the following chemical inventory lists or exempt:

Country	Inventory	Y/N	Country	Inventory	Y/N
United States	TSCA	Yes	Japan	ENCS	Yes
Euro	EINECS	Yes	Korea	KECL	Yes
Canada	DSL	Yes	New Zealand	NZIoC	Yes
Australia	AICS	Yes	Philippines	PICCS	Yes
China	IECSC	Yes	Taiwan	TCSI	Yes

Other Chemical Substances

The following chemical substances are not intentionally added in the manufacture of or formulation of this product.

No.	Substance name	No.	Substance name
1.	Adipates	30.	Nitrosamines
2.	Amide /Amines and Aromatic Amines	31.	Nitrosatable Substance
3.	Azo compounds	32.	N-Ethy-toluenesulfonamide (ortho/para)
4.	Biocide/Pesticide	33.	Nonylphenol
5.	Blowing agent	34.	Octyl- or Nonylphenols or -phenoethoxylates;
6.	Brominated & Chlorinated substances	35.	Organic tin compounds/Alkyltin compounds
7.	Chlorophenols	36.	O-alkyl (C<=10,Incl. Cycloalkyl) (Me,Et,n-Pr or I-Pr)-phosphonofluoridates
8.	Chlorinated aromatic hydrocarbons	37.	O-alkyl (C<=10,incl. Cyclically)N,N-dialkyl (Me,Et,n-Pr or I-Pr) phosphoramidocyanidates
9.	Chlorinated plastic, Polyvinyl chloride (PVC) & its blends, Polyvinylidene chloride & its blends	38.	O-alkyl (C<=10,incl. Cycloalkyl) S-2-dialkyl (Me,Et,n-Pr or I-Pr) -aminoethyl alkyl (Me,Et,n-Pr,I-Pr) phosphonothiolate and its alkylated or protonated salts
10.	Dioxins	39.	S-2-dialkyl (Me,Et, n-Pr or I-Pr)-aminoethyl= hydrogen= alkyl(Me,Et,n-Pr,I-Pr) phosphonothiolate and its alkylated or protonated salts
11.	Ditertbutyl peroxide	40.	O-alkyl (C<=10 ,incl. cycloalkyl) O-2-dialkyl (Me, Et, n-Pr or i-Pr) -aminoethyl alkyl (Me, Et, n-Pr or I-Pr) phosphonites and its alkylated or protonated salts
12.	Enamel	41.	O-2-dialkyletyl (Me, Et, n-Pr or i-Pr) = hydrogen = alkyl (Me, Et, n- Pr or i-Pr) phosphonites and its alkylated or protonated salts
13.	Epoxy derivatives	42.	Optical Brighteners
14.	Ethylene Glycol Ethers	43.	Perfluorinated Chemicals
15.	Flame retardant	44.	Phenols
16.	Fragrances	45.	Phthalates
17.	Genetic Modified Organism	46.	Polybrominated Biphenyls
18.	Isocyanates	47.	Polybrominated Diphenyl Ethers
19.	Halogen (Cl, Br, F)	48.	Polychlorinated Naphthalenes
20.	Halogenated Phenols	49.	Polychlorinated and polybrominated Biphenyls
21.	Hydrofluorocarbon, Perfluorocarbon	50.	Polychlorinated and polybrominated Terphenyls
22.	Long-chained chlorinated paraffins	51.	Polycyclic aromatic hydrocarbons
23.	Medium-chained chlorinated paraffins	52.	Quartz
24.	Melamine and derivatives	53.	Radioactive substances
25.	Microbial	54.	Recycled materials
26.	Mineral Oil Aromatic Hydrocarbons	55.	Silicone / Siloxane
27.	Mineral Oil Saturated Hydrocarbons	56.	Shortchain Chlorinated Paraffins
28.	Natural rubber or latex	57.	Softeners
29.	Nano Materials		

Additional information on the health and safety aspects of our product is listed in the SDS of the product. Please contact our Technical Service Department for any other technical enquiry and clarification.

The information supplied here is valid for 1 year from the date of issuance or will be updated when appropriate or changes made in any of the regulatory. User is advised to revisit to check for any update.

Disclaimer

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